

Idaho State Board of Pharmacy

1199 W Shoreline Lane Ste 303 Boise, Idaho 83702-9103 http://bop.idaho.gov P.O. Box 83720 Boise, Idaho 83720-0067 208.334.2356 208.334.3536 fax

APPLICATION FOR PHARMACY REGISTRATION

Annual Fee: \$100 per registration

All applications that involve new	construction or structural chan	ges must include floor plans	
Proposed Opening Date:	Previous license/registration w/ldaho Board of Pharmacy?		
Pharmacy Name:			
Address:	City:	Zip:	
Pharmacy Phone:	Fax:		
Contact Person:	Phone:	Email:	
Pharmacy Owner:(Attach listing of office	cers, partners, etc., with addres	ss and phone for each)	
Type of	f Operation – Check all that app	ply:	
☐ Retail Pharmacy ☐ Institutional Pharmacy	☐ Ster ☐ Nuc ☐ Tele ☐ Ren	Service Pharmacy rile Product Preparation clear Pharmacy epharmacy Across State Lines mote Dispensing Site er	
Supplemental Registration/s – No Automated Dispensing & Store Laminar flow or other hood, b		er isolator	
Have any of the applicants had – If yes Conviction relating to the distribution of dru	•		
Felony convictions under federal, state or I	local laws? No Yes		
Suspensions or revocation of licensure for by federal, state or local laws of any licens			
Have any applications for licensure or regis	stration been denied by any federa	al, state or local agency? \square No \square Yes	
Pharmacist in Charge:	rmacist - Print	Phone:	
Signature of Pharmacist in Charge:		Date:	



Idaho State Board of Pharmacy

1199 W Shoreline Lane Ste 303 Boise, Idaho 83702-9103 http://bop.idaho.gov P.O. Box 83720 Boise, Idaho 83720-0067 208.334.2356 208.334.3536 fax

Pharmacy Management - Responsibility Checklist

**You <u>must</u> attach a list of ALL currently employed Pharmacists, student pharmacists & pharmacy technicians **

The Board of Pharmacy holds the director of pharmacy and/or the pharmacist in charge of each pharmacy responsible for all pharmacy related matters. The following is a <u>non-inclusive</u> list of Board Rules that relate to the responsibilities of pharmacists moving into either of these roles. Ensure that your pharmacy has the current edition of the Idaho Pharmacy Laws & Rules prior to reviewing the following.

206.03. Inventory on PIC Change. A complete controlled substance inventory must be conducted in the event of a PIC change on or by the first day of employment of the incoming PIC. (3-21-12)

301. PIC Responsibilities.

The PIC is responsible for the management, and must maintain full and complete control, of every part of the pharmacy and its regulated operations. (3-21-12)

600.02. Corresponding and Individual Responsibility. The pharmacy registrant and the PIC or director each have corresponding and individual responsibility for compliance with the law and these rules in all aspects of the sale and the dispensing of drugs, devices, and other materials at the drug outlet, including the safe, accurate, secure, and confidential handling and storage and the preparation, compounding, distributing, or dispensing of drugs and PHI. (3-21-12)

622. **Institutional Pharmacy Director** ... The director is responsible for ensuring compliance with applicable law and for each activity of the institutional pharmacy...

Statement

Date of Change:	() Director of Pharmacy () Pharmacist in Charge
RPh License No.	Name:
PLAC	CE OF EMPLOYMENT
Pharmacy License # F	Pharmacy Name:
City:	Zip Code:
Phone:	Fax:
I certify that I have read and understan director of pharmacy and/or PIC.	d the above-mentioned Rules related to the role of the
Signature	Date

License Number	Pharmacists	
Registration Number	Student Pharmacists/Pharmacy Technicians	

005. BOARD OFFICE INFORMATION.

- **01. Street Address.** The office is located at 1199 Shoreline Lane, Suite 303, Boise, Idaho. (3-21-12)
- **02. Mailing Address**. The mailing address is P.O. Box 83720, Boise, Idaho 83720-0067. (3-21-12)
- **O3. Telephone Number**. The telephone number is (208) 334-2356. (3-21-12)
- **04. Fax Number**. The fax number is (208) 334-3536. (3-21-12)
- **05. Electronic Address.** The website address is http://bop.idaho.gov. (3-21-12)
- **06. Office Hours**. The office hours are 8 a.m. to 5 p.m., Mountain Time, Monday through Friday, excluding state holidays. (3-21-12)

006. PUBLIC RECORDS ACT COMPLIANCE.

Board of Pharmacy records and filings are subject to compliance with the Idaho Public Records Act, Title 9, Chapter 3, Idaho Code. (3-21-12)

007. OFFICIAL BOARD JOURNAL.

The official journal of the Board is the Idaho Board of Pharmacy Newsletter. A link to recent versions of the newsletter is posted on the Board's website and copies may be obtained from the Board office. Board licensees and registrants are presumed to have knowledge of the contents of the newsletter on the date of publication. The newsletter may be used in administrative hearings as proof of notification. (3-21-12)

008. MAINTENANCE, RETENTION, AND INSPECTION OF RECORDS.

- **O1.** Records Maintenance and Retention Requirement. Unless an alternative standard is stated for a specified record type, form, or format, records required to evidence compliance with statutes or rules enforced by the Board must be maintained as required and retained in a readily retrievable form and location for at least three (3) years.

 (3-21-12)
- **02. Records Subject to Board Inspection.** Records created, maintained, or retained by Board licensees or registrants in compliance with statutes or rules enforced by the Board must be made available for inspection upon request by Board inspectors or authorized agents. It is unlawful to refuse to permit or to obstruct a Board inspection. (3-21-12)

009. POLICIES AND PROCEDURES.

Policies and procedures required by this chapter must be written and maintained onsite or immediately retrievable in electronic form, operationally implemented and enforced, and updated or revised as necessary to maintain compliance with these rules. (3-21-12)

010. DEFINITIONS AND ABBREVIATIONS (A -- I).

- **01.** Accredited School or College of Pharmacy. A school or college that meets the minimum standards of the ACPE and appears on its list of accredited schools or colleges of pharmacy. (3-21-12)
 - **02.** ACPE. Accreditation Council for Pharmacy Education. (3-21-12)
- **03. Acute Care Hospital.** A facility in which concentrated medical and nursing care is provided by, or under the supervision of, physicians on a twenty-four (24) hour basis to inpatients experiencing acute illnesses. (3-21-12)
- **04. ADS -- Automated Dispensing and Storage**. A mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing, or distribution of drugs and that collects, controls, and maintains transaction information. (3-21-12)

12. Exclusive Arrangements. Participation in a plan or agreement that compromises the quality or extent of professional services or limits access to provider facilities at the expense of public health or welfare.

(3-21-12)

- **13. Failure to Report**. Failing to report to the Board any violation of statutes or rules pertaining to the practice of pharmacy or any act that endangers the health, safety, or welfare of patients or the public. (3-21-12)
 - **14. Failure to Follow Board Order.** Failure to follow an order of the Board. (3-21-12)

501. GROUNDS FOR DISCIPLINE.

The Board may refuse to issue or renew or may suspend, revoke, or restrict the registration of an individual on one (1) or more of the grounds provided in section 54-1726, Idaho Code. (3-21-12)

502. USE OF FALSE INFORMATION PROHIBITED.

Use of false information in connection with the prescribing, delivering, administering, or dispensing of a controlled substance or other drug product is prohibited. (3-21-12)

503. PRESCRIPTION DELIVERY RESTRICTIONS.

A pharmacist must not participate in any arrangement or agreement whereby filled prescriptions may be left at, picked up from, accepted by, or delivered to any place of business not registered as a pharmacy except that a pharmacist or a pharmacy, by means of its agent, may deliver filled prescriptions to the patient, the patient's residence, the hospital or other institutional facility in which the patient is convalescing, or if a non-controlled substance, to the patient's licensed or registered healthcare provider.

(3-21-12)

504. UNLAWFUL ADVERTISING.

- **01. Unlawful Advertising or Inducements.** A licensee or registrant may not promote or induce, directly or indirectly, the provision of professional services or products through the dissemination of a public communication that contains a false, misleading, or deceptive statement or claim. (3-21-12)
- **02.** Advertising Controlled Substances Prohibited. A person must not advertise to the public controlled substances, Schedules I through V, in any manner, and a pharmacy must not display these products to their patrons or members of the public. (3-21-12)

505. -- 599. (RESERVED)

Subchapter E -- Drug Outlet Practice Standards (Rules 600 through 699 -- Drug Outlet Practice Standards)

600. PHARMACY REGISTRANT AND PIC OR DIRECTOR.

- **01. Designated PIC or Director Required.** A pharmacy must not be without a designated PIC or director for more than thirty (30) sequential days. (3-21-12)
- **O2.** Corresponding and Individual Responsibility. The pharmacy registrant and the PIC or director each have corresponding and individual responsibility for compliance with the law and these rules in all aspects of the sale and the dispensing of drugs, devices, and other materials at the drug outlet, including the safe, accurate, secure, and confidential handling and storage and the preparation, compounding, distributing, or dispensing of drugs and PHI.

 (3-21-12)

601. PHARMACY SPACE AND FIXTURES.

O1. Preparation Area Standards. A pharmacy must be well-lit, ventilated, temperature controlled, and have sufficient floor and counter space to avoid overcrowding and to allow the pharmacy to be maintained in a clean and sanitary condition appropriate for the safe preparation and compounding of prescriptions. (3-21-12)

- **02. Equipment and Fixture Standards.** A pharmacy must be equipped with a sink with hot and cold water, appropriate fixtures for waste disposal, and refrigerated storage equipment of reasonable capacity. (3-21-12)
- **03.** Additional Retail Pharmacy Requirements. A retail pharmacy that is new or remodeled after the effective date of this rule must: (3-21-12)
- a. Provide and maintain a patient consultation area that affords the patient auditory and visual privacy, is accessible through an entrance and exit that does not require the patient to enter or traverse any part of the prescription preparation or drug storage areas, and is compliant with the Americans with Disabilities Act; and (3-21-12)

b. Include a lavatory facility in the pharmacy restricted to pharmacy staff. (3-21-12)

602. PHARMACY TECHNICAL EQUIPMENT.

- **01. Technical Equipment.** A pharmacy must have appropriate technical equipment to maintain the electronic recordkeeping requirements of these rules and any additional equipment and supplies required by its scope of practice to ensure public safety. (3-21-12)
- **Q2. PHI Transmission Equipment Location**. A non-institutional pharmacy that uses a fax machine or other equipment to electronically send or receive PHI must locate and maintain the equipment within the secured pharmacy. (3-21-12)
- **O3. Separate Telephone**. A pharmacy must have a separate and distinct telephone line from that of the business that must not be answerable by non-pharmacy personnel. If a pharmacy uses an automatic answering system, messages must not be retrieved or pharmacy services performed by non-pharmacy personnel. (3-21-12)

603. PHARMACY REFERENCES.

Required pharmacy references include the latest hard copy or electronic editions and supplements of the following: (3-21-12)

01. Pharmacy Laws and Rules. Idaho Pharmacy Laws and Rules. (3-21-12)

O2. Current Pharmacy Reference. One (1) of the following current pharmacy references: (3-21-12)

a. Facts and Comparisons; (3-21-12)

b. Clinical Pharmacology; (3-21-12)

c. Micromedex; or (3-21-12)

d. Lexicomp. (3-21-12)

03. Additional Current Pharmacy Reference. One (1) additional current pharmacy reference relevant to the practice setting. (3-21-12)

604. PHARMACY PRODUCT STORAGE AND REMOVAL.

Prescription drugs, devices, and other products restricted to sale or dispensing by, or under the supervision of, a pharmacist must be stored in the pharmacy and must not be sold, delivered, or otherwise removed from a pharmacy unless a pharmacist is present, except as allowed by these rules for emergency access to an institutional pharmacy. In an institutional facility these restricted products may also be stored in an alternative designated area that is appropriately equipped to ensure compliance with drug product storage requirements, to provide adequate security and protection from diversion, and that otherwise complies with applicable requirements of these rules. (3-21-12)

605. PHARMACY SECURITY.

101. Basic Security Standards. A pharmacy must be constructed and equipped with adequate security,

and at least while closed, utilize an alarm or other comparable monitoring system to protect its equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use. Pharmacies without an alarm or other monitoring system as of the effective date of this rule must comply with this rule upon completion of a structural remodel.

(3-21-12)

- **Non-Institutional Pharmacy Security During Pharmacist Absence.** A non-institutional pharmacy must be closed for business and secured during all times a pharmacist is not present except for brief pharmacist absences within the business establishment or to perform professional services in the peripheral areas immediately outside of the pharmacy. (3-21-12)
- 03. Structural Security Requirements. If a pharmacy is located within an establishment that is open to the public for business at times when a pharmacist is not present, the pharmacy must be totally enclosed in a manner sufficient to provide adequate security for the pharmacy, as required by this rule and approved by the Board.
- **a.** Pharmacy walls must extend to the roof or the pharmacy must be similarly secured from unauthorized entry. (3-21-12)
 - **b.** Solid core or metal doors are required.

(3-21-12)

- c. Doors and other access points must be constructed in a manner that the hinge hardware is accessible only from inside of the pharmacy and must be equipped with locking devices. (3-21-12)
- **d.** If used, a "drop box" or "mail slot" allowing delivery of prescription drug orders to the pharmacy during hours closed must be appropriately secured against theft, and the pharmacy hours must be prominently visible to the person depositing the prescription drug order. Prescriptions must not be accepted for delivery to the pharmacy or for depositing in the drop box by non-pharmacy employees of a retail establishment. (3-21-12)
- **04.** Restricted Access to the Pharmacy. No one must be allowed entrance to the closed and secured pharmacy unless under the direct supervision of a pharmacist or except as permitted by these rules for an institutional pharmacy.

 (3-21-12)

606. PHARMACY NOTIFICATION AND ADVERTISING OF HOURS OPEN FOR BUSINESS.

- **O1. Notification of Business Hours.** A pharmacy must notify the Board and prominently display the hours open to the public for business, if applicable, on or adjacent to its entrance and the entrance of the business establishment in which it is located if the open hours are different. (3-21-12)
- **Notification of Change of Business Hours**. The Board must be notified of changes to the hours that a pharmacy is open to the public for business, including changes resulting in differential hours, at least seven (7) days prior to the change except changes of hours in recognition of state holidays set forth in Section 73-108, Idaho Code. A change of hours for a holiday must be prominently posted for public notice at least seven (7) days in advance.

 (3-21-12)

607. PHARMACY STAFFING AND RATIO.

- **01. Staffing.** A pharmacy must be staffed sufficiently to allow for appropriate supervision, to otherwise operate in compliance with the law, and if applicable, to remain open during the hours posted as open to the public for business. (3-21-12)
- **Ratio.** The ratio of pharmacists to student pharmacists and technicians may not exceed one (1) pharmacist for every six (6) student pharmacists and technicians in total in any practice setting. A pharmacist must not operate a pharmacy, allow the operation of a pharmacy, or be required to operate a pharmacy with a ratio that results in, or would reasonably be expected to result in, an unreasonable risk of harm to public health, safety, or welfare.

 (3-21-12)

608. PHARMACY STRUCTURAL REMODEL APPROVAL.

Prior to the commencement of structural remodeling that impacts the periphery or security of an existing pharmacy, a floor plan must be submitted to, and approved by, the Board. The prescription preparation area (including the patient consultation, merchandising, and waiting areas, if applicable), storeroom, restroom, partitions (including, but not limited to, walls, doors, and windows), trade fixtures, and appropriate elevations must be indicated on the submitted floor plan.

(3-21-12)

609. PHARMACY CHANGE OF OWNERSHIP OR PERMANENT CLOSING.

- **91. Board Notification.** The registrant must notify the Board of a pharmacy's change of ownership or permanent closure at least ten (10) days prior to the event. The notice must include: (3-21-12)
 - **a.** The name and address of the pharmacy to be sold or closed; (3-21-12)
 - **b.** The date of sale or closure; (3-21-12)
 - **c.** The name and address of the business acquiring the prescription inventory; and (3-21-12)
- **d.** The name and address of the pharmacy acquiring the prescription files and patient profiles in compliance with the records retention requirement. (3-21-12)
- **Public Notice.** A registrant must notify the general public of the pharmacy's permanent closing at least ten (10) days prior to closing. The notice must include the date of closure and the new location of the prescription files. Notice must be provided by prominent posting in a public area of the pharmacy. (3-21-12)
- **O3.** Pharmacy Signs. Unless sold and transferred to another pharmacy operator, a registrant must remove or completely cover each sign and other exterior indication that the premises was a pharmacy within thirty (30) days after the date a pharmacy permanently ceases operations. (3-21-12)
- **04.** Transfer or Other Disposition of Drugs and Prescription Files. The PIC of a pharmacy that ceases operation must adequately secure and protect the drug product inventory from diversion, deterioration, or other damage until lawful transfer or disposition and must retain a closing inventory of controlled substances.

(3-21-12)

O5. Pharmacy Change of Ownership. A change of ownership of a currently registered pharmacy will require the submission and approval of a new pharmacy registration application but will not require an onsite inspection prior to issuance of a pharmacy registration unless structural remodeling occurs. (3-21-12)

610. -- 619. (RESERVED)

620. INSTITUTIONAL FACILITY -- PRACTICE OF PHARMACY AND ADMINISTRATION AND CONTROL OF DRUGS AND DEVICES.

These institutional facility rules are applicable to the practice of pharmacy and the administration and control of drugs and devices within institutional facilities or by persons employed by them. (3-21-12)

621. INSTITUTIONAL FACILITY WITH ONSITE PHARMACY -- MINIMUM RESPONSIBILITIES.

- **01. Institutional Pharmacy Staffing.** The director must be assisted by a sufficient number of additional pharmacists, student pharmacists, and technicians as may be required to operate the pharmacy competently, safely, and adequately to meet the needs of the patients of the facility. (3-21-12)
- **02. Inventory Management**. The professional staff of the institutional facility must cooperate with the director to manage the responsibilities of ordering, administering, and accounting for drugs, devices, and other pharmaceutical materials. (3-21-12)
- **03. Prescribers Authorized by Institutional Facility**. The institutional facility must designate and notify the pharmacy of the prescribers authorized to issue drug orders for facility patients. (3-21-12)